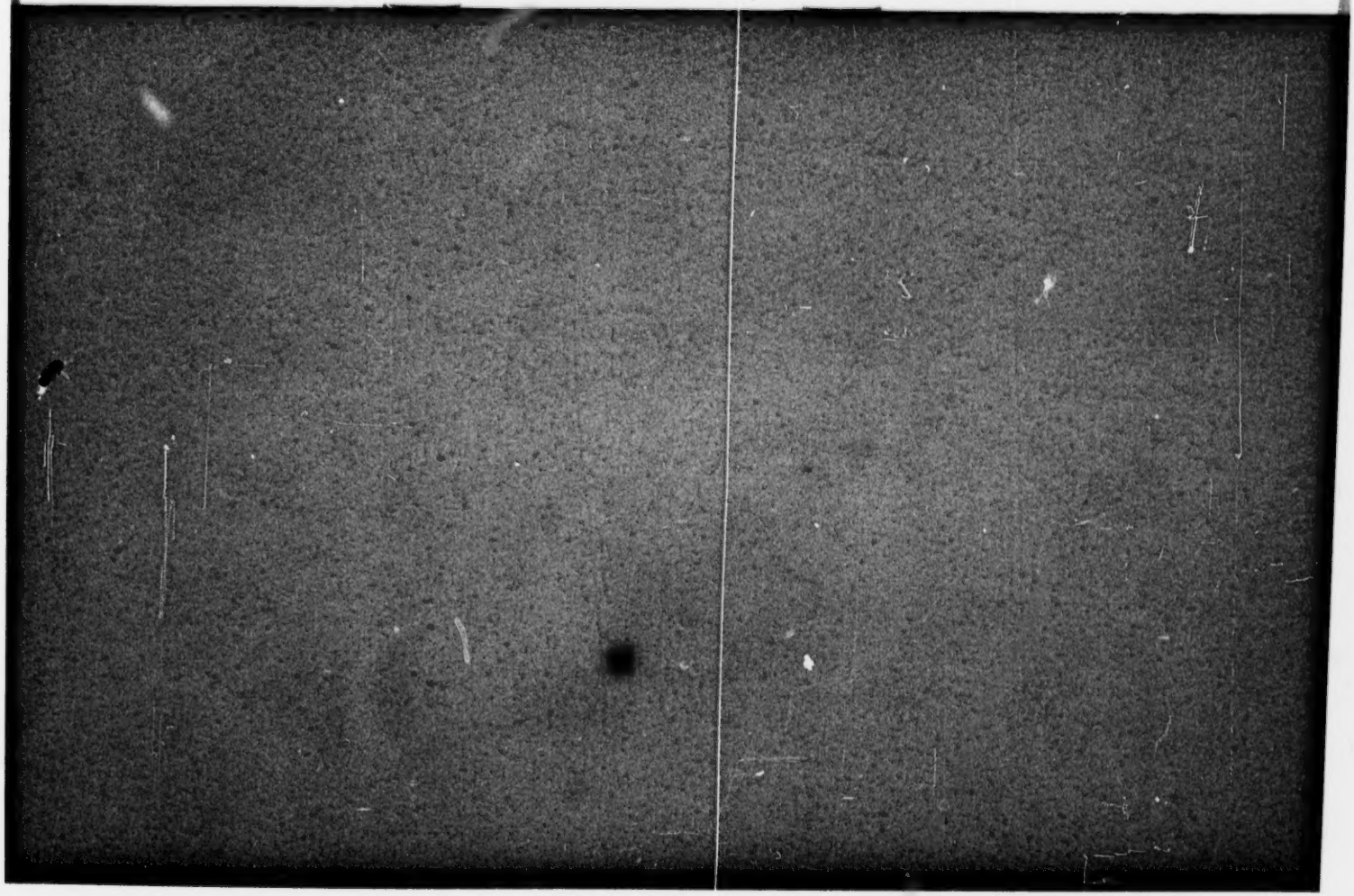

LIBRARY
SUPREME COURT, U. S.

Supreme Court, U. S.
FILED
FEB 19 1975
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-574

NATIONAL NUTRITIONAL FOODS ASSOCIATION, SOLGAR CO., INC., and NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS,

Petitioners,

—against—

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

Respondent.

REPLY BRIEF FOR PETITIONERS

MILTON A. BASS,
ROBERT ULLMAN,
SHELDON S. LUSTIGMAN,
Counsel for Petitioners,
747 Third Avenue,
New York, N. Y. 10017.
(212) 751-9494

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-574

NATIONAL NUTRITIONAL FOODS ASSOCIATION, SOLGAR CO., INC., and NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS,

Petitioners,

—against—

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

Respondent.

REPLY BRIEF FOR PETITIONERS

Petitioners respectfully submit the instant reply to Respondent's brief filed herein on February 15, 1975.

I.

Respondent's formulation (Br. p. 2) of the first question presented by the instant petition misstates the nature of the issue presented to this Court. The issue is not whether a standard of identity can be promulgated, but whether a standard of identity under §401 of the Federal Food, Drug, and Cosmestic Act can prohibit the sale of nonconforming and properly labeled nonstandard products. Respondent's contention (Br. p. 9) that under a standard of identity the agency may exclude wholesome ingredients from the stand-

ard is not relevant in these proceedings. Here, the agency is seeking to prevent the sale of nonconforming products *outside* the standard, despite proper and clear labeling. This position is in direct conflict with the spirit and language of this Court's holding in *62 Cases of Jam* v. *United States*, 340 U.S. 593 (1951).

This Court has dealt with §401 on only two occasions in the more than 36 years of the statute's history. The interpretation of this Court's decisions with respect to §401 should be resolved by the Court in light of the widespread and nationwide implications of the exclusionary power asserted by the agency.

II.

Respondent (Br. p. 2) has even more seriously misstated the second question presented in the petition. Here, the opposition brief totally misses the issue, which is limited solely to restrictions on the sale of individual vitamins or minerals.[1] The only reference to this aspect is in the footnote in Respondent's brief at page 10 where the position is taken that "the issue is not the identity *per se* of each vitamin and minerals [sic]." It is respectfully submitted that the "identity" of each vitamin and mineral when sold separately is precisely the issue to be considered under the "standard of identity" provisions of §401 of the Act. Here, the agency has gone beyond the scope of §401 by limiting individual vitamins and minerals in terms of quantity with-

[1] As noted in the petition (page 8), separate and apart from the standard of identity for combination products, the regulations also impose restrictions on the separate sale of individual vitamins or minerals. See §80.1(b)(2), Appendix D, D4.

out any reference to identity.[2] In this respect, too, clarification by the Court of this far-reaching statute is necessary and appropriate.

III.

Respondent has essentially failed to discuss the issues raised by the third question presented for *certiorari*. Respondent's discussion of the jurisdictional issue[3] completely overlooks the novel and unprecedented invocation of a concept of "pendant jurisdiction" by a Court of Appeals.

IV.

It would be rare indeed to find facts which more clearly present the need for inquiry into the administrative process, than those in the instant case.[4] See also *KFC National Management Corp.* v. *NLRB*, 497 F.2d 298 (2d Cir., 1974) where Judge Friendly in an earlier unreported order had directed the agency to file a statement detailing the participation of Board officials.[5] The interpretation of the *Morgan* cases affects the actions of all administrative agencies and should be resolved by this Court.

---

[2] Usefulness of foods for special dietary use has no relationship to the question of identity under §401. In fact, this Court in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218 (1943) upheld the exclusion of a "useful ingredient" from the standard of identity which was established for farina.

[3] Br. p. 12, n. 16.

[4] Respondent's quotation from the Court of Appeals Decision (Br. p. 14, n. 18) merely notes that no showing of "bad faith" was made. Bad faith, however, was never an issue in this case.

[5] The significance of the *KFC* case is discussed in detail in the Supplemental Brief filed with this Court by Petitioners under Docket No. 73-1700.

CONCLUSION

For the reasons set forth herein, as well as in Petitioners' prior filing, the petition for a writ of *certiorari* should be granted.

Respectfully submitted,

MILTON A. BASS,
ROBERT ULLMAN,
SHELDON S. LUSTIGMAN,
Counsel for Petitioners